

ASSAY CARTRIDGES AND METHODS OF USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATION

[0001] Reference is made to application Ser. No. 10/744, 726, filed Dec. 23, 2003, now U.S. Pat. No. 7,497,997 B2, and U.S. Provisional application Ser. No. 60/436,569, filed Dec. 26, 2002. The disclosures of each of these applications are incorporated herein by reference.

[0002] This utility application claims priority to U.S. Provisional application Ser. Nos. 61/283,677, filed on Dec. 7, 2009, 61/283,927, filed on Dec. 10, 2009, and 61/284,276, filed on Dec. 16, 2009. The disclosures of each of these applications are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY-SPONSORED RESEARCH

[0003] This invention was made with federal support under HHS 200-2007-19346 awarded by the Department of Health and Human Services. The U.S. government has certain rights in the invention.

FIELD OF THE INVENTION

[0004] This application relates to apparatuses, systems, kits and methods for conducting chemical, biochemical and/or biological assays on a sample. These apparatuses include assay cartridges and cartridge readers for conducting these assays. The application also describes electrode arrays for use in assays, methods of preparing and using these electrode arrays and diagnostic devices comprising the arrays. These electrode arrays may be incorporated into the cartridges and apparatuses of the invention.

BACKGROUND OF THE INVENTION

[0005] Clinical measurements have been traditionally carried out in central clinical labs using large clinical analyzers that can handle large numbers of samples in batch mode. These laboratories are staffed by trained personnel that are capable of maintaining and running these complex analyzers. There is a growing desire to move clinical measurements from the central lab to the "point of care", e.g., the emergency room, hospital bedside, physicians office, home, etc. Point of care measurements allow a care provider or patient to quickly make decisions based on diagnostic information, as opposed to having to wait hours or days to receive laboratory results from a clinical lab. The difficulty in developing point of care diagnostic systems has been making them small enough and easy enough to use so that they can be used by unskilled operators in decentralized clinical settings, but at the same time maintaining the low cost, diverse assay menu, and/or high performance of tests carried out on traditional clinical analyzers in central laboratories.

SUMMARY OF THE INVENTION

[0006] Therefore, the present invention provides an assay cartridge that may be used to conduct a biological assay in a cartridge reader. The assay cartridge and accompanying reader include numerous features to facilitate sample collection and assay processing.

[0007] In one embodiment, the invention provides an assay cartridge including an indicator window to facilitate sample

collection and processing in the assay cartridge. The assay cartridge includes a sample chamber, a sample indicator window and an optical path from a reflecting surface to said indicator window, wherein the reflecting surface reflects a sample level in the sample chamber to the indicator window. Alternatively, the assay cartridge may include a sample chamber, a sample indicator window, a reflecting surface, and an optical path connecting the sample chamber, the sample indicator window and the reflecting surface. The sample indicator window may include an indicating feature, e.g., an indicating line that indicates a fluid level within the sample chamber, wherein the level is selected from the group consisting of a sample minimum, a sample maximum, a target level and a combination thereof. Alternatively, the indicating feature is a boundary of the indicator window.

[0008] The reflecting surface may be a mirrored surface and in one embodiment, the cartridge comprises a cartridge body and the reflecting surface is provided by total internal reflection at an angled surface in the cartridge body. The angled surface may be configured such that an angle of incidence along the optical path is greater than a critical angle for total internal reflection at the reflecting surface. In one embodiment, the angled surface is provided by a surface of a cavity within the cartridge body such that light traveling through the cartridge body along the optical path intersects an air-body interface at the cavity surface and is reflected along the optical path to the indicator window. For example, the angle of incidence may be greater than or equal to about 43 degrees. In one specific embodiment, the angle of incidence is about 45 degrees. The cartridge body may comprise a material with a refractive index greater than or equal to 1.46 and may include a cartridge top, a cartridge bottom and a cover layer mated to the cartridge bottom and the optical path may be provided by the cartridge top. The sample chamber in the assay cartridge may be connected to an overflow chamber via a sample overflow conduit, wherein the overflow chamber is connected to a sample vent port via a vent conduit, optionally positioned at or near the top of the overflow chamber.

[0009] The invention also provides a method of determining a fluid level in an assay cartridge that includes a sample indicator window. That method includes the steps of (a) adding a volume of fluid to the sample chamber, wherein the fluid level is reflected via the optical path to the indicator window; (b) viewing the fluid level in the sample indicator window; and (c) comparing the fluid level relative to an indicating feature on the sample indicator window.

[0010] The invention also provides an assay cartridge including a sample chamber configured to receive and process a sample deposited on an applicator stick. Such an assay cartridge may be used to analyze a sample collected with an applicator stick comprising a shaft and a sample collection head (e.g., a swab), the cartridge comprising a sample chamber having an elongated cavity that has a first region and a second region, wherein the first and second regions are oriented at an angle with respect to each other and the angle is selected to bend the shaft upon insertion of the applicator stick into the sample chamber and promote fracture of the shaft, wherein the sample chamber comprises a sample head retention feature. The retention feature may be selected from the group consisting of a barb, a shelf, and combinations thereof. In one embodiment, the retention feature is a barb and the barb is angled to allow for insertion of the shaft into the sample chamber and to prevent removal of the collection head from the sample chamber. The sample chamber may include